OCT 2.2 2007

Applicant claims small entity status. See 37 CFR 1.27

TO/SB/17_(05-07)

Approved for use through 05/31/2007. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

ork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number Under the Pa

| Effective on 12/ | | Complete if Known | | | |
|---|----------------------|----------------------|-------------------|--|--|
| ant to the Consolidated Appropriations Act, 2005 (H.R. 4818). | | Application Number | 09/709,045 | | |
| E IKAN | ISMITTAL | Filing Date | November 10, 2000 | | |
| For FY | 2007 | First Named Inventor | M. Ridgon Lentz | | |
| | ahia Can 27 CED 4 27 | Examiner Name | Lorraine Spector | | |
| cant claims small entity status. See 37 CFR 1.27 | | Art Unit | 1647 | | |
| OUNT OF PAYMENT | (\$) 180.00 | Attorney Docket No. | LEN 102 | | |

| TOTAL AMOUNT OF PAYMEN | Г (\$) | 180.00 | Attorney Docket No. | LEN 102 | | |
|---|------------|---------------------------|---------------------------|------------------------------|--------------------------|--|
| METHOD OF PAYMENT (check all that apply) | | | | | | |
| Check Credit Card | | | | | | |
| ✓ Deposit Account Deposit | Account No | ımber: <u>50-3129</u> | Deposit Account | Name: Pabst Pate | nt Group LLP | |
| For the above-identified d | eposit acc | ount, the Director is he | reby authorized to: (che | ck all that apply) | | |
| ✓ Charge fee(s) indic | ated belov | v | Charge fee(| s) indicated below, e | xcept for the filing fee | |
| | | or underpayments of fe | ee(s) ✓ Credit any o | verpayments | | |
| under 37 CFR 1.16 WARNING: Information on this form information and authorization on P1 | may becor | ne public. Credit card in | formation should not be i | ncluded on this form. I | Provide credit card | |
| FEE CALCULATION | | | | | | |
| 1. BASIC FILING, SEARCH, FI | AND EX | | RCH FEES EXA | AMINATION FEES | | |
| Application Type Fe | - /A: — | all Entity ee (\$) | Small Entity Fee (\$) Fe | Small Entity e (\$) Fee (\$) | Fees Paid (\$) | |
| | | <u>50</u> 500 | | 00 100 | <u> </u> | |
| / · · · · · · · · · · · · · · · · · · · | | 00 100 | | 30 65 | | |
| • | 00 1 | 00 300 | | 60 80 | | |
| Reissue 30 | 00 1 | 50 500 | | 00 300 | | |
| Provisional 20 | 00 1 | 00 0 | 0 | 0 0 | | |
| 2. EXCESS CLAIM FEES | | | | | Small Entity | |
| Fee Description | 4: D.::- | | | <u>Fee (\$)</u> 50 | <u>Fee (\$)</u> 25 | |
| Each claim over 20 (inclu- Each independent claim o | | | | 200 | 100 | |
| Multiple dependent claims | | idding Keissues) | | 360 | 180 | |
| • • | a Claims | Fee (\$) Fe | e Paid (\$) | • • • | Dependent Claims | |
| 20 or HP = | | x = | | Fee (\$) | Fee Paid (\$) | |
| HP = highest number of total claim | | | | | | |
| indep. Claims Extr | a Ciaims | | <u> Paid (\$)</u> | | | |
| - 3 or HP = x = HP = highest number of independent claims paid for, if greater than 3. | | | | | | |
| 3. APPLICATION SIZE FEE | | | | | | |
| If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer | | | | | | |
| listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | | | |
| Total Sheets <u>Extra Sheets</u> <u>Number of each additional 50 or fraction thereof</u> <u>Fee (\$)</u> <u>Fee Paid (\$)</u> | | | | | | |
| 100 = / 50 = (round up to a whole number) x = 4. OTHER FEE(S) Fees Paid (\$) | | | | | | |
| Non-English Specification,) \$130 fee (no small entity discount) | | | | | | |
| Other (e.g., late filing surpharge): Information Disclosure Statement 180.00 | | | | | | |
| | | | | | | |

Registration No. 31,284 Telephone 404-879-2151 Signature (Attorney/Agent) Date October 19, 2007 Name (Print/Type) Patrea L. Pabst

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

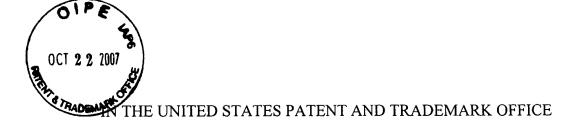
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

| Up the Paperwork Reduction Act of 1995, no person | ns are required to respond to a col | lection of information unless it displays a valid OMB control number. |
|--|-------------------------------------|---|
| | Application Number | 09/709,045 |
| TRANSMITTAL | Filing Date | November 10, 2000 |
| FORM | First Named Inventor | M. Ridgon Lentz |
| | Art Unit | 1647 |
| (to be used for all correspondence after initial filing) | Examiner Name | Lorraine Spector |
| Total Number of Pages in This Submission | Attorney Docket Number | LEN 102 |
| | | |

| Total | Number of Pages in | This Submission | | | | | EN IU | | | |
|---|--|---|-------|---|--|----------|--------|------|--|---|
| | | | = 116 | | | | | | | |
| ENCLOSURES (Check all that apply) | | | | | | | | | | |
| ✓ | Fee Transmittal Fo | orm | | Drawii | ing(s) | | | | After A | Ilowance Communication to TC |
| | Fee Attach | ed | | Licens | sing-related Papers | | | | | I Communication to Board eals and Interferences |
| | Extension of Time Express Abandonr Information Disclost Certified Copy of F Document(s) Reply to Missing P Incomplete Applica Reply to M | leclaration(s) Request ment Request sure Statement Priority | | Provis Power Chang Termin Reque | on on to Convert to a sional Application or of Attorney, Revoca ge of Correspondence inal Disclaimer est for Refund Number of CD(s) Landscape Table on | ce Addr | ress | Fift | (Appea Proprie Status Other I below) ht (8) y-seve | Enclosure(s) (please Identify |
| | | SIGNA | TURE | OF A | PPLICANT, AT | FORN | IEY. O | R AG | ENT | |
| Firm Na | ame Pa | bst Patent Gro | | | , | | , | • | | |
| Signatu | ire (| 7(| | | | | | | | |
| Printed | name Par | trea L. Pabst | | | | | | | | |
| Date October 19, 2007 | | | | Reg | j. No. | 31,284 | | | | |
| CERTIFICATE OF TRANSMISSION/MAILING | | | | | | | | | | |
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: | | | | | | | | | | |
| Signatu | ire | Clay | dic | <u>ک</u> | Loter. | . | | | | |
| Typed o | or printed name | Claudia Lore | enz | | | | | | Date | October 19, 2007 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Applicant:

M. Rigdon Lentz

Serial No.:

09/709,045

Art Unit:

1647

Filed:

November 10, 2000

Examiner:

Lorraine Spector

For:

METHOD AND SYSTEM TO REMOVE CYTOKINE INHIBITOR IN

PATIENTS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicant submits a Supplemental Information Disclosure Statement, including eight (8) pages of Form PTO-1449, and copies of the fifty-seven (57) documents cited therein. This application is allowable and is currently in an interference at the Board of Patent Appeals and Interferences.

This Supplemental Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(d) after a Notice of Appeal. The Commissioner is hereby authorized to charge \$180.00, the fee set forth under 37 C.F.R. § 1.17(p), to Account No. 50-3129. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 50-1329.

10/23/2007 AAHMADI 888888011 503129 89789045

01 FC:1806

189.00 DA

U.S.S.N.:

09/709,045

Filed:

November 10, 2000

SUPPLEMENTAL INFORMATION

DISCLOSURE STATEMENT

WINTER, et al. "Synthetic human antibodies and a strategy for protein engineering,"

FEBS Letters, 430:92-94(1998).

YAMAZAKI et al. Biocompatibility of plasma separator of an improved cellulose acetate

hollow fiber. In: Sieberth HG (ed). Plasma Exchange. New York: fk Schattauer, 45-51(1980).

ZIEGLER-HEITBROCK, et al., "Tumor necrosis factor as effector molecule in

monocyte-mediated cytotoxicity," Cancer Res 46:5947-52 (1986).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has

been conducted or that no better art exists. Moreover, Applicant invites the Examiner to make an

independent evaluation of the cited art to determine its relevance to the subject matter of the

present application. Applicant is of the opinion that his claims patentably distinguish over the art

referred to herein, either alone or in combination.

Respectfully submitted,

Patrea L. Pabst

Reg. No. 31,284

Dated: October 19, 2007

PABST PATENT GROUP LLP

400 Colony Square, Suite 1200

1201 Peachtree Street

Atlanta, Georgia 30361

(404) 879-2151 (Telephone)

(404) 879-2160 (Fax)

7

Filed:

November 10, 2000 SUPPLEMENTAL INFORMATION

DISCLOSURE STATEMENT

U.S. Patents

| Number | Issue Date | Patentee | Class/Subclass |
|-----------|------------|-------------------|----------------|
| 4,439,332 | 03-27-1984 | Frank | 507/225 |
| 4,708,713 | 11-24-1987 | Lentz | 604/5 |
| 4,863,611 | 09-05-1989 | Bernstein | 210/661 |
| 5,135,919 | 08-04-1992 | Folkman et al. | 514/56 |
| 5,147,638 | 09-15-1992 | Esmon, et al. | 424/085.8 |
| 5,290,807 | 03-01-1994 | Folkman, et al. | 514/475 |
| 5,610,279 | 03-11-1997 | Brockhaus | 530/387.3 |
| 5,629,327 | 05-13-1997 | D'Amato | 514/323 |
| 5,639,725 | 06-17-1997 | O'Reilly, et al. | 514/012 |
| 5,698,586 | 12-16-1997 | Kishimoto, et al. | 514/475 |
| 5,712,291 | 01-27-1998 | D'Amato | 514/323 |
| 5,713,491 | 02-03-1998 | Hughes, et al. | 222/129 |
| 5,716,981 | 02-10-1998 | Hunter, et al. | 514/449 |
| 5,733,876 | 03-31-1998 | O'Reilly et al. | 514/12 |
| 5,712,291 | 06-27-1998 | D'Amato | 514/323 |
| 5,808,029 | 09-15-1998 | Brockhaus | 536/23.5 |
| 5,817,522 | 10-06-1998 | Goodman, et al. | 436/165 |
| 6,133,431 | 10-17-2000 | Yusada | 530/413 |
| 6,379,708 | 04-30-2002 | Howell, et al. | 424/529 |

U.S. Patent Applications

| Number | Publication Date | <u>Inventor</u> | Class/Subclass |
|-----------------|------------------|-----------------|----------------|
| 2005-0244371 A1 | 06-14-2005 | Lentz | 424/085 |
| 2005-0265996 A1 | 12-01-2005 | Lentz | 424/133 |
| 09/709,045 | 11-10-2000 | Lentz | 424/0085 |
| 09/699,003 | 10-26-2000 | Lentz | 604/008 |

Foreign Documents

| <u>Number</u> | Publication Date | <u>Patentee</u> | <u>Country</u> |
|---------------|------------------|-----------------|----------------|
| WO 99/61085 A | 12-02-1999 | Lentz | PCT |

Filed: November 10, 2000 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Publications

AGISHI, Anion-blood contact (ABC reaction) in patients treated by LDL apheresis with dextran sulfate-cellulose column while receiving ACE inhibitors (letter). JAMA; 271:195-6(1994).

ANDREWS, et al., "Characterization of the receptor for tumor necrosis factor (TNF) and lymphotoxin LT) on human T lymphocytes: TNF and LT differ in their receptor binding properties and the induction of MHC class I proteins on a human CD4+ T cell hybridoma," *J Immunol* 144:2582-2591 (1990).

BANYAI et al., "Therapeutic efficiency of lipoprotein(a) reduction by low-density lipoprotein immunoapheresis," *Metabolism* 47(9):1058-1064 (1998).

BONAVIDA, et al., (eds), Tumor Necrosis Factor/Cachecin and Related Cytokines. Int. Conf. Tumor Necrosis Factor and Related Cytotoxins, Heidelberg, 1987, pp. 7-19 (Karger, Basel1988).

CHEN, et al., "Soluble TNF- α Receptors are constitutively shed and downregulate adhesion molecule expression in malignant gliomas," *J. Neuropathol. Exp. Neurol.* 56(5):541-550 (1997).

CLACKSON, et al., "Making of antibody fragments using phage display libraries," *Nature* 352: 624-688 (1991).

COLMAN, et al., <u>Hemostatsis and Th rombosis: Basic Principles and Clinical Practice</u> 2nd. Edition (Colman, et al., eds.) pp. 242-267 J.B. Lippincott: Philadelphia, PA, 1987.

CYTOLOGIC, "Unleash Immunotherapy," CytoLogic non CDA info.doc , pp.1-10 (April 27, 2006).

DAUGHERTY, et al., "Polymerase chain reaction facilitates the cloning, CDR-grafting, and rapid expression of a murine monoclonal antibody directed against the CD18 component of leukocyte integrins," *Nucl. Acids Res.* 19: 2471-2476 (1991).

EY, et al., "Isolation of pure IgG₁, IgG_{2a}, and IgG_{2b} immunoglobins from mouse serum using protein A-Sepharose," *Immunochemistry* 15:429-436 (1978).

FEINMAN, et al., "Tumor necrosis factor is an important mediator of tumor cell killing by human monocytes," *J Immunol* 138:635 (1987).

Filed: November 10, 2000 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

GATANAGA, et al., "Purification and characterization of an inhibitor (soluble tumor necrosis factor receptor) for tumor necrosis factor and lymphotoxin obtained from the serum ultrafiltrates of human cancer patients," *Proceedings of the National Academy of the USA* 87(22):8781-8784 (1990).

GATANAGA, et al., "Identification of TNF-LT blocking factor(s) in the serum and ultrafiltrates of human cancer patients," *Lymphokine Res* 9:225-9 (1990).

GUYTON and HALL, Textbook of Medical Physiology 9th ed. Pp. 299

HARANAKA, et al, "Cytotoxic activity of tumor necrosis factor (TNF) on human cancer cells in vitro," *Jpn J Exp Med* 51:191 (1981).

HARLOW et al., *Antibodies, A Laboratory Manual*, Chapter 13, "Immunoaffinity Purification," pp. 511-552, 1988

Hemostasis and Thrombosis: Basic Principles and Clinical Practice 2nd Ed., Colman, R.W., et al., p. 263 (J.B.Lippincott, Philadelphia, PA 1987),

HONG et al., "Intercellular adhesion molecule-1 expression induced by interleukin (IL)-1 beta or an IL-1 beta fragment is blocked by an IL-1 receptor antagonist and a soluble IL-1 receptor," *Journal of Neuroimmunology*, 44(2):163-170 (1993).

HOWARD, et al., Vaccinia virus homologues of the Shope fibroma virus inverted terminal repeat proteins and a discontinuous ORF related to the tumor necrosis factor receptor family," *Virology* 180(2):633-47 (1991).

IBM Technical Disclosure Bulletin, Vol 19, No 3. August 1976 pp. 765-768

JABLONSKA & PEITRUSKA, "Release of soluble tumor necrosis factor receptors from polymorphonuclear cells of breast cancer patients," Arch Immunol Ther Exp (Warsz). 45(5-6):449-53 (1997).

JANEWAY, et al. <u>Immunobiology: The Immune System in Health and Disease</u>, 4th Ed. Pp.102

KABAT, et al., <u>Sequences of Proteins of Immunological Interest</u> 4th Ed. (U.S. Dept. Health and Human Services, Bethesda, MD, 1987).

KAMINSKA, et al. "Clinical significance of serum cytokine measurements in untreated colorectal cancer patients: soluble tumor necrosis factor receptor type I--an independent prognostic factor," *Tumour Biol.* 26(4):186-94(2005).

Filed: November 10, 2000 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

KAMINSKA, et al "Pretreatment serum levels of cytokines and cytokine receptors in patients with non-small cell lung cancer, and correlations with clinicopathological features and prognosis. M-CSF - an independent prognostic factor," *Oncology* 70(2):115-25(2006).

KOJIMA, et al. "Effect of nafamostat mesilate on bradykinin generation during lowdensity lipoprotein apheresis using a dextran sulfate cellulose column," *ASAIO Trans* 37: 644-8(1991).

LANGKOPF, et al., "Soluble tumor necrosis factor receptors as prognostic factors in cancer patients," *Lancet* 344:57-58 (1994).

LENTZ, "Continuous whole blood UltraPheresis procedure in patients with metastatic cancer," *Journal of Biological Response Modifiers* 8(5):511-527 (1989).

LENTZ, "The role of therapeutic apheresis in the treatment of cancer: a review," *Therapeutic Apheresis* 3(1):40-49 (1999).

MARUYAMA, et al. "Evidence for aberrant activation of the interleukin-2 autocrine loop by HTLV-1-encoded p40x and T3/Ti complex triggering," *Cell.* 48(2):343-350(1987).

MATHIAS, et al., "Activation of the Sphingomyelin signaling pathway intact EL4 cells and in a cell-free system by IL-lb," *Science* 259:519-522 (1993).

MATSCHINER, et al., <u>Current Advances in Vitamin K Research</u>, pp. 135-140, John W. Suttie, ed. (Elsevier Science Publishing Co., Inc. 1988)

MITTEREGGER, et al., "In vitro cell culture systems as the basis for an extracorporeal blood purification strategy in multiorgan failure treatment", *Ther Apher.*, 3(3):257-63 (1999).

NATIONAL CANCER INSTITUTE, "Biological Therapies for Cancer: Questions and Answers," National Cancer Institute FactSheet (08-16-2004).

OLD, Antitumor activity of microbial products and tumor necrosis factor, and Bonavida B, et al., (eds): Tumor Necrosis Factor/Cachecin and Related Cytokines, Basell, Karger, p7 (1988).

PALASZYNSKI," Synthetic C-terminal peptide of IL-1 functions as a binding domain as well as an antagonist for the IL-1 receptor," *Biochemical and Biophysical Research Communications*, 147(1):204-211(1987).

PENNICA et al., "Characterization of a recombinant extracellular domain of the type 1 tumor necrosis factor receptor: evidence for tumor necrosis factor-alpha induced receptor aggregationm," *Biochemistry* 31(4):1134-1141(1992).

U.S.S.N.: 09/

09/709,045

Filed: November 10, 2000 SUPPLEMENTAL INFORMATION

DISCLOSURE STATEMENT

PENNICA et al.," Biochemical characterization of the extracellular domain of the 75-kilodalton tumor necrosis factor receptor," *Biochemistry* 32(12): 3131-3138(1993).

PHILIP & EPSTEIN, "Tumor necrosis factor as immunomodulator and mediator of monocyte cytotoxicity induced by itself, Gamma-interferon and Interleukin-1," *Nature* 323(6083):86-87 (1986).

Product description: catalog number AB-225-PB catalog of R&D Systems. (1994).

Product description: catalog number AB-226-PB catalog of R&D Systems (1994).

Product description: catalog numbers FAB225F catalog of R&D Systems (1998).

Product description: catalog numbers MAB225 catalog of R&D Systems (1998).,

Product description: catalog numbers AF-425-PB catalog of R&D Systems (1998).

Product description: of antibody AHR3912. Biosource catalog

SELINSKY, et al., "Multifaceted inhibition of anti-tumor immune mechanisms by soluble tumour necrosis factor receptor type-1," *Immunology* 94(1):88-93 (1998).

SHIBATA, et al., "Changes of cell-mediated immunity with an advance of cancer-relation to the th1/th2 balance and inhibitors of th1 cytokines", *Biotherapy*, 12(5):715-17 (1998).

SIDHU AND BOLLON, "Tumor necrosis factor activities and cancer therapy – A perspective" *Pharmacol. Ther.* 57:79-128 (1993).

TETTA, et al., "Continuous plasma filtration coupled with sorbents," *Kidney International* 53(66):S186-S189 (1998).

URBAN, et al., "Tumor necrosis factor: A potent effector molecule for tumor cell killing by activated macrophages," *Proc Natl Acad Sce USA* 83:5233-37 (1986).

VAN ZEE, et al., "Tumor necrosis factor soluble receptors circulate during experimental and clinical inflammation and can protect against excessive tumor necrosis factor alpha *in vitro* and *in vivo*" *PNAS* 89:4845-4849 (1992).

VERMA et al., "Antibody engineering: comparison of bacterial, yeast, insect and mammalian expression systems," *Journal of Immunological Methods*, 216(1-2):165-181(1998).

WARZOCHA, et al. "Tumor necrosis factor ligand-receptor system can predict treatment outcome in lymphoma patients," *J Clin Oncol.* 15(2):499-508(1997).